



## SPL Pathways

Pathways for successful creation & submission of SPL R4 Documents  
Scenarios eBooks Series

# **SPL Examples**

## **NDC Labeler Code & Establishment Registration**

Version 1.0

**Purpose:** This SPL R4 training Pathways eBook has examples of the SPL stylesheet view of the NDC Labeler Code and Establishment Registration documents.

This Pathways eBook is to be considered as a companion document to the SPL training eBooks related to the creation and submission of NDC Labeler Code and Establishment Registration SPL documents.

Note: For information on creating NDC Labeler Code and Establishment SPL files, see the SPL training eBooks accessible via this web page: <http://spl-work-group.wikispaces.com/SPL+eBooks+-+Graphic+Guides>

SPL stylesheet view renders data in SPL files in a standardized format independent of the SPL authoring software utilized to generate the SPL document.

## NDC Labeler Code Request – Request for an NDC Labeler Code

Acme Inc -----

Labeler's Name

9-digit DUNS Number - No hyphens

Missing labeler code - This is a request for a labeler code.

Product Information	
Product Type	
	NDC LABELER CODE REQUEST

**Labeler - Acme Inc (752913821) NDC Labeler Code:**

Contact	Address	Telephone Number	Email Address
Sherry Thompson	Address: 325 Fairway Avenue City, State, Zip: Towson, MD, 20221 Country: USA	+1-888-521-2958	sherry.thompson@acme.com

Revised: 03/2010

Contact Person's

Address for contact person

Telephone number using correct format

E-mail address using correct format

Acme Inc

## NDA Labeler Code SPL with already assigned NDC Labeler Code

Acme Inc

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Already assigned 4- or 5- digit Labeler code  
(No leading zeros which form a 6-digit labeler code)

### Product Information

Product Type

NDC LABELER CODE REQUEST

**Labeler -** Acme Inc (752913821) **NDC Labeler Code:** 76182

Contact	Address	Telephone Number	Email Address
Sherry Thompson	Address: 325 Fairway Avenue City, State, Zip: Towson, MD, 20221 Country: USA	+1-888-521-2958	sherry.thompson@acme.com

Revised: 03/2010

Acme Inc

## Establishment Registration SPL document

Notes:

1. Registrants should include **ALL** drug establishments owned/operated in **ONE** Establishment Registration SPL
2. **NEVER** alter the setID once you submit either a **test or official** SPL file.
3. This example has two drug establishments included in one file.

Company for owner/operator of drug establishment(s)		Registrant's DUNS Number	Document Type	
Product Information				
Product Type			ESTABLISHMENT REGISTRATION	

  

Registrant - Acme Inc (871192812)			
Contact	Address	Telephone Number	Email Address
Paul Jacobsen	Address: 17 Philadelphia Avenue City, State, Zip: Towson, MD, 19001 Country: USA	+1-888-201-5821	paul.jacobsen@acme.com

↑ Registrant contact person's name

Contact person's address

Contact person's telephone number

Contact person's e-mail address

## Establishment located in the USA

Establishment's name		DUNS Number (9-digit) No hyphens	FEI Number (7- or 10-digits)	Type of operation (except US Agent and Import)
Establishment				
Name	Address	ID/FEI	Operations	
Acme Manufacturing USA	Address: 17 Philadelphia Avenue City, State, Zip: Towson, MD, 19001 Country: USA	441912813/3000149281	manufacture	
Contact	Address	Telephone Number	Email Address	
Paul Jacobsen	Address: 17 Philadelphia Avenue City, State, Zip: Towson, MD, 19001 Country: USA	+1-888-201-5821	paul.jacobsen@acme.com	

## Establishment not located in the USA

Establishment		DUNS Number (9-digit)		Missing FEI indicates request for FEI		Multiple types operation permitted if applicable (except US agent or Import)	
Name	Address	ID/FEI					
Acme Manufacturing - France	Address: 314 Provence Rue City, State, Zip: Nice, -, 33151 Country: FRA	999210521				manufacture, api manufacture	
Contact	Address	Telephone Number	Email Address				
Etienne Bouvier	Address: 19 Champs Elysees City, State, Zip: Paris, -, 151295 Country: FRA	+32-592-5821	etienne.bouvier@acme.fr				
US Agent (ID)	Address	Telephone Number	Email Address				
Templeton Agents (594921022)		+1-888-125-5821	jan.tolson@templeton.com				
Importer (ID)	Address	Telephone Number	Email Address				
Franklin Imports (075821321)		+1-444-291-5921	james.costas@franklin.com				

Revised: 03/2010

Current registration year  
Enter format as YYYYMMDD

US agent must be present if country code is not "USA"

Import company name & DUNS Number

Establishment contact's address does not have to be identical to establishment's address

3-letter country code

Enter dash "-" if there is no state